Management Provisions on Registration of Medical Devices

Chapter 1 General Provisions

Article 1 The Provisions is hereby enacted in accordance with *the Regulation on Supervision and Administration of Medical Devices*, and with a view to standardize the registration of medical devices (hereinafter referred to as "MD") and to guarantee the safety and effectiveness of MD.

Article 2 All the MD to be sold and used in China shall be applied for registration in accordance with the Provisions. The MD without such registration may not be sold and applied in China.

Article 3 The state implements MD registration by way of classification.

The MD under class I produced by domestic enterprises shall be examined by the drug and MD administrations affiliated to governments of municipal level. A Registration Certificate of MD product is to be issued to qualified applicant upon approval.

The MD under class II produced by domestic enterprises shall be examined by the drug and MD administrations affiliated to governments of provincial level. A Registration Certificate of MD product is to be issued to qualified applicant upon approval.

The MD produced by overseas enterprises shall be examined by the State Pharmaceutical Administration. A Registration Certificate of MD product is to be issued to qualified applicant upon approval.

The MD under class III produced by domestic enterprises shall be examined by the State Pharmaceutical Administration. A Registration Certificate of MD product is to be issued to qualified applicant upon approval.

The MD produced by domestic enterprises refers to the MD whose final production procedures are completed within China.

The MD produced by overseas enterprises refers to the MD whose final production procedures are completed outside China.

The MD produced in Taiwan, Hong Kong and Macao applied to be sold and used in Chinese mainland shall be examined by the State Pharmaceutical Administration.

Article 4 The Registration Certificate of MD products shall be printed by the State Pharmaceutical Administration with a uniform standard.

(I) For the MD under class I produced by domestic enterprises, the applicant may directly apply for registration of formal production. For the MD under class II and III produced by domestic enterprises, the applicant shall first apply for registration of trial production, with a term of validity for two (2) years. Starting from the seventh month after such registration of trial production, relevant applicants may apply for registration of formal production , with a term of validity for four (4) years.

The registration numbers are arranged as follows:

X1 Yaoguanxie (X2) Zi XXXX3 No. X4 XX5 XXXX6

Among which:

X1 refers to the abbreviation for the location of registration (country name/provinces, autonomous regions and municipalities directly under the central government, or provinces, autonomous regions + cities);

X2 refers to the mode of registration (trial production or formal production);

XXXX3 refers to the year of registration;

X4 refers to the type of MD products;

XX5 refers to the expiration year of trial production (for trial production) or the type code of MD products (for formal production);

XXXX6 refers to the registration serial number.

A Ratification Form on the Production of MD Products attached to the Registration Certificate is to be used together with the certificate.

(II) The Registration Certificate granted to overseas applicants will have a term of validity for four (4) years, and the registration numbers are arranged as follows.

Guoyaoguan xie (Jin) XXXX1 No. X2 XX3 XXXX4

Among which:

XXXX1 refers to the year of registration

X2 refers to the type of MD products

XX3 refers to the type code of MD products

XXXX4 refers to the registration serial number

A Ratification Form on the Production of MD Products attached to the Registration Certificate is to be used together with the certificate.

Chapter 2 Registration of MD Produced by Domestic Enterprises

Article 5 For the MD under class I produced by domestic enterprises, the applicant shall submit the following materials when applying for registration:

(I) Qualification certificate of the MD production enterprise;
(II) Specifications of the MD product applied for registration and related notes and explanations;
(III) A self-test report on performance of the product;
(IV) A description of the existing resources, conditions and capacity of quality management (including means of test) for the production;
(V) Instruction manual of the product; and
(VI) A statement of guarantee on the authenticity of the materials submitted.

Article 6 For the MD under class II and III produced by domestic enterprises, the applicant shall submit the following materials when applying for registration of trial production:

(I) Qualification certificate of the MD production enterprise;
(II) A technical report of the product;
(III) An analysis on risks of the safety;
(IV) Specifications of the MD product applied for registration and related notes and explanations;
(V) A self-test report on performance of the product;
(VI) A test report on the MD with registration of trial production issued within one (1) year (half a year for biological materials) by the MD quality testing institutions certified by the State Pharmaceutical Administration;
(VII) Clinical trial reports from more than two (2) clinical trial bases. These reports shall be provided in the way stipulated by *the Provisions on Report Items of Clinical Trials for MD Registration* (see Appendix). The clinical trials shall be conducted in compliance with *the Provisions on Clinical Trials for MD Products;*
(VIII) Instruction manual of the product; and
(IX) A statement of guarantee on the authenticity of the materials submitted.

Article 7 For the MD under class II and III produced by domestic enterprises, the applicant shall submit the following materials when applying for registration of formal production :

(I) Qualification certificate of the MD production enterprise;
(II) Copies of the Registration Certificate for trial production;
(III) Specifications for the MD product applied for registration;
(IV) A perfection report on improvements made during the trial production;
(V) Valid certificate for inspection on the enterprise's quality system;
(VI) A test report on the MD with registration of formal production issued within one (1) year by the MD quality testing institutions certified by the State Pharmaceutical Administration;
(VII) A quality tracking report of the product; and
(VIII) A statement of guarantee on the authenticity of the materials submitted

Article 8 The applicant shall apply for a renewal of the registration within six (6)months prior to the expiration of the Registration Certificate for formal production.

For the MD under class I, the applicant shall submit the following materials when applying for renewal of the registration:

(I) Qualification certificate of the MD production enterprise;
(II) Copies of the original Registration Certificate for formal production;
(III) Specifications for the MD product applied for registration;
(IV) A quality tracking report of the product; and
(V) A statement of guarantee on the authenticity of the materials submitted.

For the MD under class II and III, the applicant shall submit the following materials when applying for renewal of the registration:

(I) Qualification certificate of the MD production enterprise;
(II) Copies of the original Registration Certificate for formal production;
(III) A test report on the MD with registration of formal production issued within one (1) year by the MD quality testing institutions certified by the State Pharmaceutical Administration;
(IV) Valid certificate for inspection on the enterprise's quality system;
(V) Specifications for the MD product applied for registration and related notes and explanations;
(VI) A quality tracking report of the product; and
(VII) A statement of guarantee on the authenticity of the materials submitted.

Article 9 For the MD under class II and III, relevant enterprises shall pass the examinations on its quality system when applying for registration of formal production .

Such examination on quality system shall be conducted in accordance with *the Provisions on Examination for Quality System of MD Production Enterprises*.

Article 10 After submitting the required documents for registration of trial production, the applicant may directly apply for registration of formal production in the following circumstances:

(I) The relevant enterprise has been granted with **Certificate of GB/T19001+YY/T0287 or GB/T19002+YY/T0288** (*Quality System, Specialized Requirements for the Application of MD*) issued by the certification agencies on quality system designated by the State Pharmaceutical Administration, and the MD product applied for registration falls into the same category with the MD product that has been registered for formal production ; or

(II) The differences in structure and function between the MD product applied for registration and the MD product of the same category that has been registered will not have material impact on the safety and effectiveness.

Chapter 3 Registration of MD Produced by Overseas Enterprises

Article 11 For the MD produced by overseas enterprises, the applicant shall submit the following materials when applying for registration:

(I) Qualification certificate of the MD producer;
(II) Qualification certificate of the applicant;
(III) Certificate issued by the country(region) of origin that approve or permit such MD product to enter the market of that country (region);
(IV) Technical specifications of the MD product that applies for registration (i.e. the requirements on its safety and technical performance) and corresponding means of test (two copies of such technical specifications shall be provided if the MD product falls into class III);
(V) Instruction manual of the product;
(VI) A test report on the MD issued within one (1) year by the MD quality testing institutions certified by the State Pharmaceutical Administration(applicable for the MD under class II and III);
(VII) Clinical trial reports from more than two (2) clinical trial bases. These reports shall be provided in the way stipulated by *the Provisions on Report Items of Clinical Trials for MD Registration* (see Appendix).

The clinical trials shall be conducted in compliance with *the Provisions on Clinical Trials for MD Products;*

(VIII) A statement of guarantee on quality of the product issued by the producer, who shall make a commitment in such a statement that the product to be registered and sold in China will have the same quality as the same product sold in the country (region) of origin.

(IX) A letter of authorization which designate after-sales service agencies in China, a letter of commitment and the business license of such entrusted agencies;

(X) A statement of guarantee on the authenticity of the materials submitted.

The above-mentioned documents shall have their Chinese version. The documents mentioned in (I), (II) and (III) of this Article may be submitted in photocopies, but shall be signed and sealed by the original issuing authorities or notarized by local notary offices. Other documents mentioned in this Article shall be submitted in original test with seals or signatures made by legal representatives.

Article 12 For the MD produced by overseas enterprises, the applicant shall apply for a renewal of registration within six (6) months prior to the expiration of the Registration Certificate. The following materials shall be submitted for such renewal of registration:

(I) Qualification certificate of the applicant;

(II) Copies of the original Registration Certification;

(III) Certificate issued by the country(region) of origin that approves or permits such MD product to enter the market of that country (region);

(IV) Technical specifications of the MD product that applies for registration (i.e. the requirements on its safety and technical performance) and corresponding means of test (two copies of such technical specifications shall be provided if the MD product falls into class III);

(V) Instruction manual of the product;

(VI) A test report on the MD issued within one (1) year by the MD quality testing institutions certified by the State Pharmaceutical Administration(applicable for the MD under class II and III);

(VII) A quality tracking report of the product;

(VIII) A statement of guarantee on quality of the product issued by the producer, who shall make a commitment in such a statement that the product to be registered and sold in China will have the same quality as the same product sold in the country (region) of origin.

(IX) A letter of authorization which designate after-sales service agencies in China, a letter of commitment and the business license of such entrusted agencies;

(X) A statement of guarantee on the authenticity of the materials submitted.

Article 13 An on-site inspection on the production quality system shall be conducted for the registration of the MD products under class III produced by overseas enterprises. Such on-site inspection shall be made once for every four years (as one cycle). The same type of MD products covered by the quality system that has passed such on-site inspection will not need on-site inspection for the second time within the same cycle in its application process for registration.

Chapter 4 Management of MD Registration

Article 14 The drug and MD administrations affiliated to governments of municipal level shall determine whether to approve the application for registration within thirty (30) business day after receiving all the application materials.

The drug and MD administrations affiliated to provincial governments shall determine whether to approve the application for registration within sixty (60) business day after receiving all the application materials.

The State Pharmaceutical Administrations shall determine whether to approve the application for registration within ninety (90) business day after receiving all the application materials (the time spent on overseas on-site inspection on the quality system is excluded).

Written explanations will be necessary in case of rejection.

Upon receiving all the application materials, the above-mentioned registration authorities shall issue a notice of acceptance and start counting down according to the said time limit of inspection.

During the inspection period, if the applicant is required to submit supplementary materials or clarify on certain issues, the time spent on waiting for such supplementary materials or clarifications will be excluded from the counting down of the said time limit of inspection.

Article 15 Any MD that can satisfy all the following conditions may apply for an exemption from inspection:

(I) For domestic enterprises, the relevant enterprise has been granted with **Certificate of GB/T19001+YY/T0287 or GB/T19002+YY/T0288** issued by the certificate agencies on quality system designated by the State Pharmaceutical Administration, and the MD product applied for registration is covered by such certified system;

For overseas enterprises, the relevant enterprise has been approved by related regulatory authorities of the original country on sales of its products, and has been certified by ISO 9000 system (or equivalent standard system) within the term of validity of the said approval document;

(II) The differences in structure and function between the MD product applied for registration and the MD product of the same category that has been registered will not have material impact on the safety and effectiveness.

(III) The MD product applied for registration is non-implantable;
(IV) The MD product applied for registration is free from radiation;
(V) The MD product applied for registration will not lead to serious accidents (such as death of user or operator) in case of malfunction.

Article 16 The instruction manual of the product shall be separately examined and approved in accordance with *the Management Provisions on Instruction Manuals, Labels and Packages of MD Products*, Once approved, such instruction manual may not be changed at will. To add new indications or enlarge scope of application on the registered MD, the applicant shall submit a new application for renewal of registration.

Article 17 The registration categories of MD products shall be determined in accordance with different technical structures and performance index.

Article 18 For MD product registered in parts, the applicant shall also recommend supporting products, part or parts to be used together with the registered part(s) and provide their specifications and type codes. For any complete unit composed of parts that all have been registered, the applicant shall apply for registration of such complete unit separately.

For product registered in complete unit, the applicant shall make a list of key supporting parts. If there is any change to the performance index of a certain part, the applicant shall apply for renewal of registration.

For product that has been registered in complete unit, its composing parts can be sold with an exemption from registration.

Article 19 Alteration and re-application of the Registration Certificate

(I) In the event that any enterprise need to change its name in the Registration Certificate due to renaming or merger, the enterprise shall apply for alteration of Registration Certificate by submitting an application report, its new business license and certificate issued by

local drug and MD administrations to relevant authorities within thirty (30) business days after such change;

(II) In the event that a new product name is to be used for the same product, relevant enterprise shall apply for alteration of Registration Certificate by submitting an application report to relevant authorities;

(III) In the event that the Registration Certificate is lost or damaged, relevant enterprise shall re-apply for the same Registration Certificate by submitting an application report and a statement to assume relevant legal liabilities to relevant authorities;

(IV) In the event that any enterprise, with its name and product unchanged, needs to change its production site, the enterprise shall apply for a new Registration Certificate in the original format. Valid certificate on qualified quality system of the enterprise shall be submitted for registration.

Article 20 For alteration of the Registration Certificate, the original serial number is still valid and a "(Geng)" (meaning "altered") will be added to end of the original serial number. The date of issuance for the renewed certificate shall be the date when such alteration is approved. The term of validity shall be equivalent to the remaining term of the original certificate and the expiration date (date, month, and year) shall be clearly defined and showed on the renewed certificate. The original certificate shall be revoked when the renewed certified is issued.

Article 21 For registered MD products that have stopped operation for more than two (2), consecutive years, the Registration Certificate shall become invalid automatically. Such enterprise shall apply for new registration in case of a new starting of operation.

Article 22 Management provisions on registration of transferred MD products is to be stipulated separately.

Article 23 Medical institutions can research and develop MD for their patients, but may not put such MD into mass production during the stage of R&D. Such MD products shall be used only in the same medical institutions that research and develop it. Certificate on trial use of such MD product will be issued with a term of validity for two (2) years. If such MD product is to be mass-produced upon the expiration of the said certificate on trial use, relevant entities shall apply for approval and registration.

For such MD product under Class II, the applicant shall submit application for approval to the drug and MD administrations affiliated to governments of provincial level. The following material shall be provided in the application process:

(I) Qualification certificate of the medical institution;

(II) Specifications of the MD product;
(III) A test report on the MD issued within one (1) year by the MD quality testing institutions certified by the State Pharmaceutical Administration;
(IV) A report on clinical trials;
(V) Instrument manual of the MD product;
(VI) A statement made by the medical institution to assume any legal liabilities that may arise in relation to the MD product;
(VII) A statement of guarantee on the authenticity of the materials submitted.

Article 24 The drug and MD administrations affiliated to governments of municipal level shall report registration statistics to the drug and MD administrations affiliated to governments of provincial level on a quarterly basis. The drug and MD administrations affiliated to governments of provincial level shall report registration statistics to the State Pharmaceutical Administration on a quarterly basis. The State Pharmaceutical Administration shall periodically publish announcement on the registration of MD products.

Chapter 5 Penalties

Article 25 In the event that any enterprise or individual violates the Provisions and provides false certificates, documents and samples when applying for registration of MD, or attempt to obtain the Registration Certificate of MD by other means of deceit, the original registration authorities shall revoke the Registration Certificate of MD and shall not accept any application for registration from such enterprise or individual within two years. In addition, administrations concerned shall impose a fine in accordance with *The Regulation on Supervision and Administration of Medical Devices.*

Article 26 Enterprises that change the instruction manual and expand scope of application and indications without approval shall be deemed as enterprises that produce MD products in the absence of Registration Certificate for MD Production. According to Article 35 under *The Regulation on Supervision and Administration of Medical Devices*, the original registration authorities shall revoke the Registration Certificate of MD.

Article 27 In he event that any applicant disagree with the conclusion of the inspection on the MD product applied for registration, relevant applicant may submit a report to registration authorities concerned requiring re-examination. The original serial number of the application accepted, name of the product and producer, reasons for the demand of re-examination shall be included in the report and relevant documents and samples shall be provided.

Article 28 The drug and MD administration affiliated to the governments above provincial level shall revoke the Registration Certificate of the MD product if the safety and effectiveness of such MD cannot be guaranteed. The MD with the Registration Certificate being revoked shall not be produced, sold and applied to patients. The drug and MD administration affiliated to the governments above county level shall be responsible to treat any unqualified MD that has been produced or imported.

Article 29 In the event that the drug and MD administrations affiliated to the governments below provincial level wrongly grant Registration Certificate and breach the Provisions, the State Pharmaceutical Administration shall order them to correct their mistakes within the specified time. If such administrations fail to correct their mistakes within the specified time, the State Pharmaceutical Administration can make a public announcement to revoke the unlawful Registration Certificate of MD.

Chapter 6 Supplementary Provisions

Article 30 The power of interpretation of the Provisions pertains to the State Pharmaceutical Administration.

Article 31 This Regulation is to become effective on 10 April 2000. The original *Management Provisions on Registration of Medical Devices* (Order No.16 of the State Pharmaceutical Administration) will become expired at the same time.